

### § 33.112

(iii) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(B) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(iv) *Implementation timeline.* A detailed draft timeline for the State's implementation of the proposed waiver.

(v) *Additional information.* Additional information supporting the State's proposed waiver, including:

(A) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(B) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(C) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(D) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(E) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(vi) *Reporting targets.* Quarterly, annual, and cumulative targets for the

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comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement, and the Federal deficit requirement.

(vii) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(g) *Additional supporting information.*

(1) During the Federal review process, the Secretary may request additional supporting information from the State via the Secretary of Health and Human Services as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 33.116(b).

### § 33.112 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary of Health and Human Services for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary of Health and Human Services including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of Health and Human Services.

(2) Information relating to where copies of the application for a section

1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary of Health and Human Services for an initial waiver in accordance with the requirements set forth in § 33.108.

#### § 33.116 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of Health and Human Services determine that all elements for a complete application were documented and submitted to the Secretary of Health and Human Services.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of Health and Human Services will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(2) At the beginning of the Federal notice and comment period, the Secretary of Health and Human Services

will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of Health and Human Services on a State application for a section 1332 waiver will be issued by the Secretary of Health and Human Services no later than 180 days after the determination by the Secretary and the Secretary of Health and Human Services that a complete application was received in accordance with § 33.108.

#### § 33.120 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy, or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of Health and Human Services, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved